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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,668	07/08/2003	Antonello Covacci	CHIR-0337	6533

7590  
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Intellectual Property  
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EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

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11/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/615,668	COVACCI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-40, 44-46, 48-50, 54, 56-59 and 62-69 ~~is/are~~ pending in the application.
- 4a) Of the above claim(s) 67 and 69 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-40, 44-46, 48-50, 54, 56-59, 62-66 and 68 ~~is/are~~ rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendments**

- 1) Acknowledgment is made of Applicants' amendments filed 08/31/07 and 07/11/2007 in response to the non-final Office Action mailed 04/09/07.

### **Status of Claims**

- 2) Claims 38, 44-46, 56 and 59 have been amended via the amendment filed 08/31/07.  
Claims 41-43, 47, 51-53, 55, 60 and 61 have been canceled via the amendment filed 08/31/07.  
New claims 63-69 have been added via the amendment filed 08/31/07.  
Claims 67 and 69 are withdrawn have been withdrawn from consideration as not being directed to an elected species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.  
Claims 38-40, 44-46, 48-50, 54, 56-59, 62-66 and 68 are under examination.

### **Prior Citation of Title 35 Sections**

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

- 5) The objection to the specification made in paragraph 7(a) of the Office Action mailed 04/09/07 is withdrawn in light of Applicants' amendment to the specification.  
6) The objection to the specification made in paragraph 7(c) of the Office Action mailed 04/09/07 is withdrawn in light of Applicants' arguments.

### **Objection(s) Maintained**

- 7) The objection to the specification made in paragraph 7(b) of the Office Action mailed 04/09/07 is maintained for reasons set forth therein and herein below.

It is noted that Applicants have complied with the sequence rule with regard to some sequences depicted in Figure 3. However, the amino acid sequences of NEPIYA and EEPIYA

depicted in the middle of Figure 3 still remain non-compliant with sequence rules. The objection stands.

### **Objection to Specification**

**8)** The instant specification is objected to for the following reason:

37 CFR 1.75(d)(1) provides, in part, that 'the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'

New claim 63 is drawn to an isolated polynucleotide encoding two amino acid sequences of SEQ ID NO: 9. New claim 66 is drawn to an isolated polynucleotide encoding the amino acid sequence of SEQ ID NO: 10 and the amino acid sequence of SEQ ID NO: 9. New dependent claim 68 is drawn to the polynucleotide of claim 66 which further comprises at least nucleotide sequence of a nucleotide sequence encoding SEQ ID NO: 10 or a nucleotide sequence encoding SEQ ID NO: 9. What is claimed in these new claims lacks clear support or antecedent basis in the specification.

### **Rejection(s) Moot**

**9)** The provisional rejection of claims 41-43, 51-53 and 55 made in paragraph 9 of the Office Action mailed 04/09/07 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632, is moot in light of Applicants' cancellation of the claims.

**10)** The provisional rejection of claims 41-43 and 55 made in paragraph 10 of the Office Action mailed 04/09/07 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6 and 7 of US patent 6,090,611 (Applicants' IDS), is moot in light of Applicants' cancellation of the claims.

**11)** The rejection of claims 41, 51, 42 and 52 and those dependent therefrom made in paragraph 14 of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is moot in light of Applicants' cancellation of the claims.

**12)** The rejection of claims 41-43 and 51-53 made in paragraph 15 of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, first paragraph, as being non-enabled, is moot in light of Applicants' cancellation of the claims.

**13)** The rejection of claims 41, 42, 51 and 52 made in paragraph 17(a) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

**14)** The rejection of claims 41, 42, 51 and 52 made in paragraph 17(b) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

**15)** The rejection of claim 42 made in paragraph 17(f) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

**16)** The rejection of claim 52 made in paragraph 17(g) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

**17)** The rejection of claim 43 made in paragraph 17(h) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

**18)** The rejection of claims 42, 43, 52 and 53 made in paragraph 17(j) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

**19)** The rejection claims 41-43, 47, 51-53, 55, 60 and 61 made in paragraph 19 of the Office Action mailed 04/09/07 35 U.S.C. § 102(e)(2) as being anticipated by Cover *et al.* (US 5,403,924, filed 10/13/1992 – Applicants' IDS) ('924), is moot in light of Applicants' cancellation of the claims.

### **Rejection(s) Maintained**

**20)** The provisional rejection of claims 38-40, 44, 49, 50, 54, 59 and 62 made in paragraph 9 of the Office Action mailed 04/09/07 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632, is maintained for reasons set forth therein. Applicants cite MPEP § 804.I.B and state that upon resolution of other grounds of rejection, the obviousness-type double patenting rejection over US application 11580632 should be withdrawn and the present application allowed to issue without a

terminal disclaimer.

New claims 63-66 and 68 are now added to this rejection.

**21)** The provisional rejection of claims 38-40, 44, 49, 50, 59 and 62 made in paragraph 10 of the Office Action mailed 04/09/07 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6 and 7 of US patent 6,090,611 (Applicants' IDS), is maintained for reasons set forth therein. Applicants request that the rejection be held in abeyance pending notification of allowable subject matter in the instant application.

New claim 65 is now added to this rejection.

### **Rejection(s) Withdrawn**

**22)** The rejection of claim 46 made in paragraph 12 of the Office Action mailed 04/09/07 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claim.

**23)** The rejection of claims 48, 57, 58 and 62 made in paragraph 13 of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' arguments.

**24)** The rejection of claims 56 and 59 made in paragraph 14 of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claims.

**25)** The rejection of claims 38, 44, 56 and 59 made in paragraph 15 of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, first paragraph, as being non-enabled, is withdrawn in light of Applicants' amendment to the claims.

**26)** The rejection of claims 56 and 59 made in paragraph 17(a) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

**27)** The rejection of claims 56 and 59 made in paragraph 17(b) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

**28)** The rejection of claim 45 made in paragraph 17(c) of the Office Action mailed 04/09/07 under

35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**29)** The rejection of claims 56 and 59 made in paragraph 17(d) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

**30)** The rejection of claim 46 made in paragraph 17(e) of the Office Action mailed 04/09/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**31)** The rejection of claims 38-40, 44-46, 48-50, 56, 59, 62 made in paragraph 19 of the Office Action mailed 04/09/07 under 35 U.S.C. § 102(e)(2) as being anticipated by Cover *et al.* (US 5,403,924, filed 10/13/1992 – Applicants' IDS) ('924), is 35 U.S.C. § 102(e)(2) as being anticipated by Cover *et al.* (US 5,403,924, filed 10/13/1992 – Applicants' IDS) ('924), is withdrawn in light of Applicants' amendment to the claims and/or the base claim.

**Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)**

**32)** Claims 38-40, 44-46, 48-50 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 38 and 44 include the limitation: said polynucleotide comprises 'at least one nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 10'. The term 'at least' is not limited to one or two, but encompasses any number that is more than two. However, the instant application has no descriptive support for an isolated polynucleotide comprising at least 15 contiguous nucleotides from SEQ ID NO: 4 or which encodes at least five contiguous amino acids from the amino acid sequence of SEQ ID NO: 5, wherein said polynucleotide comprises any number of nucleotide sequences encoding SEQ ID NO: 10. *In re Rasmussen*, 650 F.2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification

as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

**33)** Claims 63, 66 and 68 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 63 is drawn to an isolated polynucleotide encoding two amino acid sequences of SEQ ID NO: 9. New claim 66 is drawn to an isolated polynucleotide encoding the amino acid sequence of SEQ ID NO: 10 and the amino acid sequence of SEQ ID NO: 9. New dependent claim 68 is drawn to the polynucleotide of claim 66 which further comprises at least one nucleotide sequence of a nucleotide sequence encoding SEQ ID NO: 10 or a nucleotide sequence encoding SEQ ID NO: 9. Applicants state that Figure 4 and pages 52 and 53 of the instant specification provide exemplary support for the new claims. However, these parts of the specification are not supportive of the generic polynucleotides claimed in the instant claims. Figure 4 is exclusively supportive of SEQ ID NO: 4 comprising a nucleotide sequence(s) therein that encodes one or two amino acid sequences of SEQ ID NO: 9 and/or SEQ ID NO: 10. Pages 52 and 53 are not supportive of a generic polynucleotide of any microbial or non-microbial origin comprising nucleotide sequences encoding two amino acid sequences of SEQ ID NO: 9, or the amino acid sequence of SEQ ID NO: 10 and the amino acid sequence of SEQ ID NO: 9, but describes specifically the *cai* gene of the G39 strain of *H. pylori* wherein the gene is SEQ ID NO: 4 that comprises nucleotide sequences encoding two amino acid sequences of SEQ ID NO: 9, or the amino acid sequence of SEQ ID NO: 10 and the amino acid sequence of SEQ ID NO: 9. The limitation 'at least' in claim 68 is not limited to one or two, but encompasses any number that is more than two. However, the instant application has no descriptive support for such a generic isolated polynucleotide which encodes more than two SEQ ID NO: 10. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).



Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**34)** Claim 68 is rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 68 is indefinite, confusing and redundant in the limitation 'nucleotide sequence of a nucleotide sequence'.

### **Rejection(s) under 35 U.S.C. § 102**

**35)** Claims 38-40, 44-46, 48-50, 54, 56-59, 62-66 and 68 are rejected under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (PNAS 90: 5791-5795, June 1993, already of record).

Instant claims are granted the effective filing date of the instant application because of the new matter identified above.

Covacci *et al.* taught an isolated polynucleotide of SEQ ID NO: 4 encoding one or two amino acid sequences of SEQ ID NO: 10, or an amino acid sequence of SEQ ID NO: 10 and SEQ ID NO: 9 and further encoding an amino acid sequence of SEQ ID NO: 9 or SEQ ID NO: 10; a vector comprising the same, and an isolated host cell transformed with the vector. The prior art polynucleotide encodes the CAI antigen of *Helicobacter pylori* comprising 1-1147 amino acids of the amino acid sequence of SEQ ID NO: 5, which is expected to be immunologically identifiable with the instantly recited amino acid sequence of SEQ ID NO: 5. See Figure 3; Materials and Methods; and Results. The prior art polynucleotide comprises at least one nucleotide sequence of the instantly recited nucleotides 3202-3216 of SEQ ID NO: 4.

Claims 38-40, 44-46, 48-50, 54, 56-59, 62-66 and 68 are anticipated by Covacci *et al.*

### **Objection(s)**

**36)** Instant claims are objected to for the following reason(s):


(a) Claims 56 and 59 are objected to for the non-italicized limitation 'Helicobacter pylori'.

(b) It is suggested that Applicants leave a single space after the limitation 'NO:' within every limitation of 'SEQ ID NO:' in the instant claims.

### Remarks

- 37) Claims 38-40, 44-46, 48-50, 54, 56-59, 62-66 and 68 stand rejected.
- 38) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the Office' Central Rightfax number 571-273-8300 via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week.
- 39) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.
- 40) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (571) 272-0898.

  
S. DEVI, PH.D.  
PRIMARY EXAMINER

November, 2007